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Petition
3/14/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1648
CLASSEN, John B.	)	Examiner: B. BRUMBACK
Appln. No.: 08/591,651	)	Washington, D.C.
Date Filed: February 12, 1996	)	March 5, 2003
For: METHOD AND COMPOSITION FOR AN EARLY VACCINE TO PROTECT AGAINST BOTH COMMON...	)	DOCKET: CLASSEN=1A Confirmation No.: 9417

PETITION TO WAIVE THE RULES UNDER 37 CFR §1.183

BOX PETITIONS
Honorable Commissioner for Patents
Washington, D.C. 20231

S i r:

Applicant petitions to the Commissioner under 37 CFR §1.183 to waive 37 CFR 1.195 and enter the declaration and exhibits filed October 18, 2002. If the PTO is unwilling to grant this relief in its entirety, applicants request that it at least waive 1.195 to the extent of entering selected references, such as the references published after the mail date of the final rejection, and giving Applicant leave to revise the declaration to present only the discussion of the selected references.

Background

The instant application is the U.S. national stage of PT/US94/08825 filed August 4, 1994, and hence is a "pre-GATT" case. The requirements for entry into the U.S. national stage were completed on February 12, 1996. The first action on the merits was mailed October 2, 1998.

An Appeal Brief was initially filed in this case on May

1, 2000. Rather than file an answer, the Examiner reopened prosecution, making, *inter alia*, a new enablement rejection.

In support of the rejection, the Examiner initially cited just "PIDJ" and "Boumpas" (see June 20, 2000 action, pages 9-10). The subsequent February 21, 2001 action additionally relied on DeStefano (ref. DU), EURODIAB (ref. EB), Graves (ref. EF), Heijbel (ref. EI), Hiltunen (ref. EL), Jefferson (ref. EQ), Karvonen (ref. EV), Bedford (ref. HD), Petousis-Harris (ref. HE), Dahlquist (ref. HK), Jefferson T.O. (ref. HP), Elliott (ref. IJ), and Anonymous (ref. IN)[1], but confined itself to a general allegation that these supported PIDJ's teaching of a lack of association between immunization schedules and type 1 diabetes. There was no specific analysis of any of these later references (and precious little of PIDJ).

Finally, in the final rejection mailed November 5, 2001, the Examiner argued that a "Classen and Classen reference" submitted by Applicant on August 17, 2001 in fact supported the enablement rejection. (There were two Classen and Classen references filed that day, "Clustering of Cases...." and "Large Decline....")

On October 18, 2002, Applicants filed a "Supplemental Amendment After Final Rejection and Submission of New Evidence", and a "Declaration (II) of Dr. Bart Classen", with attached exhibits. The Declaration discussed several pertinent references that had been published after the maildate of the final rejection, as well as the references

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[1] These references were made of record by the February 1, 2002 IDS and discussed in an exhibit, "Scientific Evidence", filed December 19, 2000.

first relied on in the February 21, 2001 action. It enclosed copies of the newly discovered references, as well as some other supporting documents discussed in detail below. A new Appellant's Brief was filed on November 5, 2002.

On November 18, 2002, the PTO mailed an advisory action which (1) entered the October 18, 2002 amendments to the claims, and (2) refused entry of the Declaration and exhibits. The PTO explained

> Submission of evidence after a final action is governed by 37 C.F.R. § 1.116. This rule requires applicant to provide good and sufficient reasons as to why the submissions are necessary and were not earlier presented. In this case, the Declaration of Dr. Classen will not be considered because the Declaration is based in part upon the consideration of newly cited art references. Applicant has not provided the statements regarding the newly cited references required under 37 C.F.R. § 1.97(e). In addition, the arguments of the Declaration are not limited to the alleged newly discovered references. The applicant has not made the showings required under 37 C.F.R. § 1.116 required for these arguments.

On December 17, 2002, Applicants requested reconsideration of the denial of entry, and petitioned for supervisory review under 37 CFR §1.181. The §1.181 petition was denied on February 10, 2003. The decision on petition conceded that 1.97(e) was not relevant, and that the Examiner should have relied on 1.195 rather than 1.116.

37 CFR 1.195 reads as follows:

> Affidavits, declarations, or exhibits submitted after the case has been appealed

> will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

Plainly, any reference published after the final rejection was mailed (November 5, 2001) could not have been presented prior to that action. This "safe haven" would embrace:

> Classen et al. "Clustering of Cases..." (2002), especially since it is really a courtesy copy of a previously submitted manuscript, which was (mis)construed by the final rejection (Declaration, Table 1, item 7);
>
> Sanjeevi et al. (2002) (Declaration, Table 1, item 8);
>
> The IOM Study (Mar. 2002) (Declaration, Table 1 item 9 and Table 2A item 12); and
>
> DeStefano (2001) (Declaration, Table 2A item 8).
>
> Classen, et al., "Vaccines and the risk of insulin-dependent diabetes (IDDM):potential mechanism of action, Medical Hypotheses (November 2001) (Declaration §12).

At least these new references should be considered, and a request for reconsideration and modification of the decision on the rule 1.181 petition has been filed on even date herewith.

The other exhibits newly submitted with the declaration were

> Classen, et al., "immunization with BCG vaccine starting after age 1 is associated

with increased risk of IDDM in Quebec (unpublished manuscript) (cited in Declaration, Table 2A, item 4)

Yang, et al., "Childhood diabetes in China:enormous variation by place and ethnic group" (1998) (Declaration Table 2A, item 3) (this reference was identified by Counsel in a MEDLINE search performed after the mail date of the final rejection)

Karvonen, et al., "Incidence of Childhood type 1 diabetes worldwide" (2000) (Declaration, Table 2A, item 2) (this reference was identified by Counsel in a MEDLINE search performed after the mail date of the final rejection)

Classen, et al., "The safety of military immunization" (2001) (Declaration, Table 1, item 10) (article is largely duplicative of p. 37-40 of the "Scientific Evidence" monograph, of record)

The 1999 physician's package insert for Merck & Co., Inc.'s M-M-R II vaccine (9265206) (Declaration §13)

"Analysis of Sample Size Requirement for Unmatched Case-Control Studies with 90% or 95% exposure in NOT ILL Group" (unpublished analysis, prepared after the final rejection) (Declaration §10)[2].

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[2] The Declaration, Table 2A, item 9, also lists. Classen, et al., Diabetologia 39:500-501 (1996). Ref. GP in the February 1, 2001 IDS was listed in the PTO-1449 with the same authors, title, publication, volume number and publication year, but different page numbers. We believe that Ref. GP may have been a preprint of the final article.

Analysis

Applicant petitions under 37 CFR 1.183 that the applicable rules be waived to permit entry of the declaration and exhibits. Credit Card Payment Form PTO-2038, authorizing charge in the amount of the petition fee of $130, is enclosed. Please charge any deficiency in the fees to deposit account 02-4035.

37 CFR 1.183 provides

> In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Commissioner or the Commissioner's designee, sua sponte, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in §1.17(h).

The statute does not require refusal of entry of declarations or exhibits after final rejection and hence is not a barrier to relief under §1.183.

We believe that this is an "extraordinary situation", in which "justice requires" relief.

First of all, the Examiner's rejection is inconsistent with the PTO's treatment of three counterpart applications that have issued as patents:

5,728,385

5,723,283

6,420,139

Not only did the PTO, in all three cases, consider the

claims to be enabling, all of the references relied on by the Examiner in connection with the instant enablement rejection were of record during the prosecution of the '139 patent.

Secondly, there is no reason that the PTO could not have made the enablement rejection when it first acted on the merits of this case, in October 1998 (already 32 months after entry into the U.S. national stage). Instead, it did not raise the issue until after Applicant, an inventor with a one-man company, had already gone to the substantial trouble and expense of an Appeal Brief. Thus, the enablement issue was not raised until June, 2000, 20 months after the first action on the merits and 52 months after entry into the national stage.

Thirdly, the February 21, 2001 rejection's string citation of references[3] was insufficient to put Applicant on

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[3] The February 21, 2001 office action merely said (paragraph bridging pp. 7-8):

> ...applicant's argument that the teachings of the PIDJ are a result of conflict of interest, rather than scientific evidence, do not seem to be supported by the general teachings of the art. See, for example, DeStafano et a. (reference DU), EURODIAB Substudy 2 Study Group (reference EB), Graves et al. (reference EF), Heijbel, et al. (reference EI), Hiltunen et al. (reference EL), Jefferson et al. (reference EQ), Karvonen et al. (reference EV), Bedford H. (reference HD), Petousis-Harris et al. (reference HE), Dahlquist et al., (reference HK), Jefferson T.O. (reference HP), Elliott et al. (reference IJ), and Anonymous (reference IN), all of record in the IDS filed 02/01/2001 (Paper #27), and all of which teach that there is no apparent association of any schedule of dosing of any known immunizations, either contributing to or reducing the incidence or severity, with type 1 diabetes mellitus.

notice as to how these references constitute evidence of nonenablement not already rebutted by the previously submitted "Scientific Evidence" exhibits.

Hence, the November 5, 2001 rejection should not have been made final, MPEP 706.07 says that all grounds of rejection should be "clearly developed" prior to final rejection. (If it hadn't been, the declaration and exhibits would have been entered as of right.)

Finally, Applicant cannot, by normal PTO procedures, force consideration of the declaration and exhibits without substantial loss of patent term.

The present application is a pre-GATT case, hence ineligible for RCE practice. Since its effective filing date is in 1994, it is ineligible for the transitional §1.129 practice, too. Filing a continuation would result in loss of pre-GATT status, resulting in a patent term expiring in 2013 (the priority application having been filed in 1993).

In contrast, if this case were allowed, and Applicants cancelled the claims rejected for double patenting,[4] and the patent issued in 2003, the patent would expire in 2020.

Consequently, pursuant to 37 CFR 1.183, Applicant petitions the Commissioner to waive 37 CFR §1.195 and direct the Examiner to enter and consider the Declaration and

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[4] There was a double patenting rejection of method claims 6, 32-33, 56-57, 101, 103, 128-148, 156, 157 and 160 over the '395 and 283 patents. Claims 156 and 157 were cancelled by substitute amendment "A" filed June 21, 2002. Claim 160 was cancelled by the October 18, 2002 amendment. Applicants would immediately cancel the method claims if the Examiner agreed to allow the kit claims.

exhibits. If this full relief is considered inappropriate under 37 CFR 1.183, then the Commissioner is requested to direct the Examiner to enter and consider specific exhibits (e.g., those published after final rejection, those discovered after final rejection, and those created after final rejection).

Respectfully submitted,

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